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SMITHKLINE BEECHAM CORPORATION d/b/a GLAXOSMITHKLINE and McKESSON CORPORATION

UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

SAN FRANCISCO DIVISION

ROSE HEFNER AS PERSONAL REPRESENTATIVE OF THE ESTATE OF IRVING HEFNER (DECEASED)

DEBORAH CITRANO JOHNSON AS PERSONAL REPRESENTATIVE OF STEPHEN CITRANO (DECEASED)

Plaintiffs,

v.

SMITHKLINE BEECHAM CORPORATION d/b/a GLAXOSMITHKLINE and McKESSON CORPORATION,

Defendants.

Case No. CV-07-6050 JL
(Pending Ruling on Motion to Relate Cases)

DEFENDANT SMITHKLINE BEECHAM CORPORATION d/b/a GLAXOSMITHKLINE'S MEMORANDUM OF LAW IN OPPOSITION TO PLAINTIFFS' MOTION TO REMAND

DATE: **January 14, 2008**
TIME: **2:00 p.m.**
COURTROOM: **15**
JUDGE: **Marilyn H. Patel**

THIS DOCUMENT RELATES TO THE FOLLOWING CASES:

Bone, et al. v. SmithKline Beecham Corporation d/b/a GlaxoSmithKline and McKesson Corporation; Case No. CV-07-5886 MHP.

Bowles, et al. v. SmithKline Beecham Corporation d/b/a GlaxoSmithKline and McKesson Corporation; Case No. CV-07-6328 JCS (ruling on motion to relate pending).

Fisher v. SmithKline Beecham Corporation d/b/a GlaxoSmithKline and McKesson Corporation; Case No. CV-07-5889 MHP.

Hall v. SmithKline Beecham Corporation d/b/a GlaxoSmithKline and McKesson Corporation; Case No. CV-07-5887 MHP.

Hefner, et al. v. SmithKline Beecham Corporation d/b/a GlaxoSmithKline and McKesson Corporation; Case No. CV-07-6050 JL (ruling on motion to relate pending).

Jefferson v. SmithKline Beecham Corporation d/b/a GlaxoSmithKline and McKesson Corporation; Case No. CV-07-5888 MHP.

Thornton v. SmithKline Beecham Corporation d/b/a GlaxoSmithKline and McKesson Corporation; Case No. CV-07-5890 MHP.

Upshaw v. SmithKline Beecham Corporation d/b/a GlaxoSmithKline and McKesson Corporation; Case No. CV-07-5891 MHP.

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I. INTRODUCTION

This is one of a number of cases that have recently been filed against defendant SMITHKLINE BEECHAM CORPORATION d/b/a GLAXOSMITHKLINE ("GSK") involving the prescription drug Avandia®. Plaintiffs' counsel, The Miller Firm, has filed Avandia cases in both state and federal courts. In the California cases only, The Miller Firm has named McKesson Corporation ("McKesson"), a California-based wholesale pharmaceutical distributor, as a defendant.[1] GSK is a citizen of Pennsylvania and Plaintiffs, Rose Hefner as Personal Representative of the Estate of Irving Hefner and Deborah Citrano Johnson as Personal Representative of Stephen Citrano ("Plaintiffs"), are citizens of Louisiana and Alabama respectively; therefore, there is complete diversity. By naming McKesson as a defendant, The Miller Firm is attempting to take advantage of the so-called "forum defendant rule" to contend that removal was procedurally defective. *See* 28 U.S.C. § 1441(b). The forum defendant rule is a waivable non-jurisdictional rule. *See Lively v. Wild Oats Mkts.*, 456 F.3d 933, 940 (9th Cir. 2006).

McKesson had not been served the time of removal, however, and its citizenship should not be considered in this Court's analysis. Moreover, Plaintiffs' joinder of McKesson is fraudulent, and the citizenship of McKesson must be disregarded for purposes of 28 U.S.C. § 1441(b).

In addition to diversity jurisdiction, this Court also has federal question, or "arising under," jurisdiction over this matter because numerous counts of Plaintiffs' complaint turn on violations of federal law.

Accordingly, Plaintiffs' Motion to Remand should be denied.

II. BACKGROUND

Plaintiffs commenced this action in the Superior Court of the State of California for the County of San Francisco on November 27, 2007, asserting claims of (1)

[1] The facts relating to McKesson are attested in the Declaration of Greg Yonko, a true and correct copy of which is attached as Exhibit "D" to the Declaration of Krista L. Cosner in Support of Notice of Removal and

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negligence; (2) negligent failure to warn; (3) negligence per se; (4) negligent misrepresentation; (5) breach of express warranty; (6) breach of implied warranty; (7) strict products liability – defective design; (8) strict products liability – manufacturing and design defect; (9) strict products liability – failure to adequately warn; (10) fraudulent misrepresentation; (11) violations of California Unfair Trade Practices and Consumer Protection Law; (12) unjust enrichment; (13) wrongful death; (14) survival action; (15) loss of consortium; and (16) punitive damages. Plaintiffs aver that collectively, "Defendants" or "Defendants GSK and McKesson," defectively designed and manufactured Avandia; concealed knowledge of unreasonably dangerous risks associated with Avandia; failed to conduct adequate and sufficient pre-clinical testing and post-marketing surveillance of Avandia; failed to provide FDA with complete and adequate information regarding the product; failed to warn consumers and/or their health care providers of certain risks associated with Avandia; failed to utilize adequate and non-misleading labeling; and made affirmative misrepresentations and omissions regarding the alleged risks of Avandia.

On November 30, 2007, prior to service of the Complaint on any party, GSK removed this action to this court, based on diversity jurisdiction under 28 U.S.C. § 1332, and federal question jurisdiction under 28 U.S.C. § 1331 and the principles set forth in *Grable & Sons Metal Prods., Inc. v. Darue Eng'g & Mfg*, 125 S.Ct. 2363 (2005).[2] *See* Notice of Removal (filed November 30, 2007). GSK also sought the transfer of this action to the Multidistrict Litigation, *In re Avandia Marketing, Sales Practices and Products Liability Litigation*, MDL 1871, and provided the JPML with notice of this action pursuant to the procedure for "tag along" actions set forth in the rules of the JPML.

Removal by SmithKline Beecham Corporation d/b/a GlaxoSmithKline (hereinafter "Cosner Decl. ISO Removal").

[2] By the date GSK's removal notice was filed, neither GSK nor McKesson had been served with Plaintiffs' Complaint. As will be described *infra*, because there is complete diversity of citizenship, and none of the parties have been properly joined and served at the time of removal, it is appropriate that this action be removed to this Court. *See Waldon v. Novartis Pharmaceuticals Corp.*, 2007 U.S. Dist. LEXIS 45809 (N.D. Cal. June 18, 2007); *see also* 28 U.S.C. § 1441(b)

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Plaintiffs now move to remand this case to the Superior Court of the State of California for the County of San Francisco. As explained below, Plaintiffs' motion is without merit, and it should be denied.

III. ARGUMENT

A. This Court Should Defer Ruling On Plaintiffs' Remand Motion Pending MDL Transfer

As GSK argued in its Motion to Stay All Proceedings Pending Transfer by the JPML, this Court should not rule on Plaintiffs' Remand Motion, but should stay this case until it is transferred to the Avandia MDL, MDL No. 1871. Allowing the transferee court to decide this and the other pending Motions to Remand will conserve the resources of the Court, will ensure consistent rulings, and will not prejudice the Plaintiffs to any significant degree. *See* Defendant's Motion to Stay All Proceedings; *see also Landis v. North Am. Co.,* 299 U.S. 248 (1936).

In the Vioxx litigation, this Court and other Northern District judges were faced with several cases removed on grounds identical to the grounds for removal of this case; namely, that McKesson was fraudulently joined, and, when its citizenship was properly disregarded, there was complete diversity of citizenship between plaintiffs and defendants. Ruling on plaintiffs' remand motions was deferred in favor of staying the cases pending transfer to the MDL on the grounds of judicial economy and consistency. *See Johnson v. Merck & Co., Inc.,* Case No. C 05-02881 MHP, Slip Op. at 2 (N.D. Cal. October 4, 2005) ("In light of the number of cases presenting issues similar to this action and the need for judicial consistency with respect to those cases, this court finds that the interest of judicial economy favors staying this action pending its transfer to [the Vioxx MDL.]."); *Johnson v. Merck & Co., Inc.* Case No. C 07-00067 WHA, Slip Op. at 4 (N.D. Cal. March 8, 2007) ("It would be an inefficient use of resources to unnecessarily duplicate the efforts of the transferee judge, who will undoubtedly face most (if not all) of the same issues in dealing with the other pending remand motions. Staying the proceedings will best serve the interests of judicial economy."); *Dante v. Merck & Co.,*

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Inc., Case No. C07-00081 JW, Slip Op. at 2 (N.D. Cal. Feb. 27, 2007) (staying case with pending remand motion where McKesson was named as co-defendant because "[i]n light of the number of other cases presenting issues similar to this action and the need for judicial consistency with respect to those cases, the Court finds that the interest of judicial economy favors staying this action pending its transfer to the MDL Proceeding"). *See also Murphy v. Merck & Co., Inc.*, No. C 06-04794 MHP, Slip Op. (N.D. Cal. Sept. 22, 2006) (staying case pending transfer to MDL proceeding where McKesson was named as a co-defendant); and *Parker v. Merck & Co., Inc.*, No. C 07-2333 SI, Slip Op. at 2 (N.D. Cal. June 26, 2007) (staying case pending transfer to MDL and deferring ruling on remand where case removed on the basis of fraudulent joinder).

For the identical reasons, this Court should defer ruling on Plaintiffs' Motion to Remand, and should stay all proceedings in this case until it is transferred to the Avandia MDL.

B. <u>This Court Has Diversity Jurisdiction Over Plaintiffs' Claims</u>

If the Court does consider Plaintiffs' motion prior to MDL transfer, it should deny Plaintiffs' motion to remand this action because there is complete diversity, because removal occurred prior to service of Plaintiffs' Complaint, and because Plaintiffs have fraudulently joined McKesson, a citizen of California, as a defendant.

1. Diversity Jurisdiction Exists Because McKesson Was Not Properly Joined and Served With Plaintiffs' Complaint Prior to Removal

Under 28 U.S.C § 1441(b), an action is removable only if none of the parties in interest, *properly joined and served* as defendants, is a citizen of the State in which such action is brought. *See* 28 U.S.C. § 1441(b) (emphasis added). McKesson, although a citizen of California, had not been served with the Plaintiffs' Complaint prior to GSK filing its Notice of Removal. Accordingly, its California citizenship does not prevent removal of this action as it occurred prior to service of process.

This is not the first time the Northern District of California has been faced with this issue. In *Waldon v. Novartis Pharmaceuticals Corp.*, 2007 U.S. Dist. LEXIS 45809

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(N.D. Cal. June 18, 2007) (J. Jenkins), plaintiff, a Georgia resident, filed suit against defendants, Novartis Pharmaceuticals Corporation (a Delaware corporation with its principal place of business in New Jersey), Novartis Corporation (a New York corporation with its principal place of business in New York), and McKesson Corporation (a Delaware corporation with its principal place of business in California), in California state court. *See id*. Prior to service the case was removed. Plaintiffs then filed a motion to remand on the grounds that there was not complete diversity amongst the parties.

The Court considered the language of 28 U.S.C. §1441(b), and determined that because McKesson had not been properly "joined and served" at the time of removal, McKesson's citizenship should be disregarded. *See id*. at *6-8. Accordingly, Judge Jenkins denied plaintiff's remand motion. *See id.* at *9.

Similarly, because none of the defendants in this action had been served with Plaintiffs' Complaint at the time of removal, McKesson's citizenship is not relevant to this Court's consideration of the propriety of removal. There is complete diversity, and removal was proper under 28 U.S.C. § 1441(b).

2. Diversity Jurisdiction Exists In This Action Because McKesson Is Fraudulently Joined

Even if McKesson had been served at the time of removal, McKesson was fraudulently joined. The fraudulent joinder doctrine requires courts to disregard the citizenship of local defendants when no viable cause of action has been stated against the resident defendant, or when evidence presented by the removing party demonstrates that there is no factual basis for the claims pleaded against the local defendant. *See Morris v. Princess Cruises, Inc.*, 236 F.3d 1061, 1067 (9th Cir. 2001); *see also Ritchey v. Upjohn Drug Co.*, 139 F. 3d 1313, 1318-19 (9th Cir. 1998). A defendant is also considered fraudulently joined when "the plaintiff fails to state a cause of action against the resident defendant, and the failure is obvious according to the settled rules of the state." *Hamilton Materials, Inc., v. Dow Chemical Corporation*, 494 F.3d 1203, 1206 (9th Cir. 2007)

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quoting *McCabe v. General Foods Corp.*, 811 F. 2d 1336, 1339 (9th Cir. 1987).

As set forth below, Plaintiffs cannot state a cause of action against the distributor McKesson because (a) Plaintiffs do not allege that McKesson handled the Avandia Plaintiffs ingested; (b) Plaintiffs' allegations against "defendants" and McKesson are inconsistent with their allegations against GSK; and (c) a wholesale distributor cannot be liable under any reasonable view of California law for alleged defects in a drug it did not make, or for the alleged inadequacy of warnings over which it had no control. In sum, there is no reasonable likelihood that Plaintiffs can prevail on their claims against McKesson, McKesson is fraudulently joined, and Plaintiffs' motion to remand must be denied.

a. Plaintiffs' Factual Allegations Against McKesson Do Not Provide an Adequate Causal Connection Between McKesson and Their Alleged Injuries

McKesson was fraudulently joined because Plaintiffs do not even allege that McKesson distributed the Avandia they took.

To state a personal injury claim against a pharmaceutical distributor, a plaintiff must, as a threshold matter, allege an actual connection between the distributor's alleged conduct and the plaintiff's purported injury. *See, e.g., Huntman v. Danek Medical, Inc.,* No. 97-2155-IEG RBB, 1998 WL 663362, at *4, *6-*7 (S.D. Cal. July 24, 1998) (strict liability, negligence, negligence per se claims require proof that alleged misconduct was directed at plaintiff or plaintiff's physician); *Service by Medallion, Inc. v. Clorox Co.,* 44 Cal. App. 4th 1807, 1818 (1996) ("In order to recover for fraud, as in any other tort, the plaintiff must plead and prove the 'detriment proximately caused' by the defendant's tortuous conduct.") (citing Cal. Civ. Code § 3333). Where, as here, plaintiffs fail to allege such a link, federal courts have recognized that non-diverse distributors are fraudulently joined and cannot defeat diversity jurisdiction. *See In re Rezulin Prods. Liab. Litig.,* 133 F. Supp. 2d 272 (S.D.N.Y. 2001) ("Rezulin II") (denying motion to remand where plaintiffs named a non-diverse defendant and alleged that a distributor

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defendant was "in the business of distributing and selling the pharmaceutical" on grounds that plaintiffs did not allege that the defendant "actually sold" the pharmaceutical product to the plaintiffs).

In its Notice of Removal, GSK noted that the factual allegations against McKesson were insufficient to establish a connection between McKesson and Plaintiffs' alleged injuries. In response, Plaintiffs charge that "GSK asks this Court to ignore the numerous times McKesson is identified by name within Plaintiffs' Complaint, and the factual detail of McKesson's activities by name." Plaintiffs' Notice of Motion and Motion to Remand with Supporting Memorandum ("Pls'. Br.") at 2:10-12.

In fact, Plaintiffs do not even allege that the Avandia ingested was distributed by McKesson, *see Lyons v. American Tobacco Co.*, 1997 U.S. Dist. LEXIS 18365, *18-19 (S.D. Ala. 1997) (there is "no better admission of fraudulent joinder of [resident defendants]" than the failure of the plaintiff "to set forth any specific factual allegations" against them). Only one paragraph of Plaintiffs' Complaint contains any direct allegations against McKesson. *See* Pls'. Compl. at ¶ 20:12-15 ("Defendant McKesson packaged, distributed, supplied, sold, placed into the stream of commerce, labeled, described, marketed, advertised, promoted, and purported to warn or to inform users regarding the risks pertaining to, and assuaged concerns about the pharmaceutical Avandia.") attached as Exhibit "A" to Cosner Decl. ISO Removal. The remaining allegations are directed at "Defendants" or against "Defendants GSK and McKesson." *See, e.g., id*. at ¶ 48 ("…defendants failed to timely and reasonably warn of material facts regarding the safety and efficacy of Avandia…"); ¶ 80 ("Defendants GSK and McKesson marketed, distributed, supplied and sold the subject product…"). Courts have held that generic allegations against multiple defendants are insufficient to create a causal connection between a plaintiff's alleged injuries and the conduct of a single defendant. *See e.g.*, *Aronis v. Merck & Co*., Inc., CIV. S-05-0486 WBS DAD, 2005 U.S. Dist. LEXIS 41531, *3 (E.D. Cal. May 3, 2005); *see also In re PPA, MDL No. 1407*, Slip Op. at 5 (W.D. Wa. Nov. 26, 2002) (allegations directed toward "defendants" or "all

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defendants" insufficient).

In *Aronis*, for example, the plaintiff alleged that her heart attack was caused by the prescription medication Vioxx, Merck – the manufacturer of Vioxx – removed the case to federal court on grounds that all the requisites of diversity jurisdiction existed. In an effort to defeat diversity, the plaintiff in that case, as here, named distributor-defendant McKesson who, like the plaintiff, was a citizen of California. The court concluded that complete diversity existed and removal was proper because the plaintiff made "no allegation that McKesson ever handled the specific pills that were allegedly the cause of her injuries." *Id.* at *3. According to the court, McKesson was fraudulently joined because "plaintiff does not allege that McKesson contributed in any way to her injuries, only that McKesson is a distributor." *Id.* at *4.

The rationale in *Aronis* applies with equal force here. Plaintiffs' allegations against McKesson are general, conclusory, and provide no more than the insufficient contention that McKesson – like many other companies – distributed Avandia to pharmacies in California. Such "bare-bones" allegations are plainly incapable of supporting a claim against McKesson and, thus, McKesson is fraudulently joined. *See id.* at *3-4 ("allegation that McKesson is a major distributor of Vioxx, even though taken as true at this state, is not enough to support a claim against McKesson").

b. Plaintiffs' Purported Allegations Against McKesson are Inconsistent with Their Central Allegations Against GSK

Second, McKesson was fraudulently joined because Plaintiffs' allegations against McKesson are inconsistent with their core allegations against GSK.

The crux of Plaintiffs' lawsuit rests on allegations regarding GSK's design and manufacture of Avandia, and assertions that GSK failed to adequately warn against Avandia's alleged side effects and concealed important safety information. *See* Pls'. Compl. at ¶¶ 21-34 (Cosner Decl. ISO Removal, Exh. "A"). Yet, Plaintiffs also purport to assert that McKesson was responsible for the warnings included in Avandia's labeling, s*ee id*. at ¶ 20:12-15, and that both "defendants" were responsible for these warnings.

See id. at ¶ 48. These allegations are inconsistent and contradictory, and courts have frequently viewed such inconsistencies as evidence of fraudulent joinder. For instance, in *Baisden v. Bayer Corp.*, 275 F.Supp. 2d 759, 762-763 (S.D. W. Va. 2003), a pharmaceutical manufacturer removed a product liability case to federal court, asserting that the plaintiff fraudulently joined a local physician to defeat diversity. *See id.* The district court agreed and denied remand. *See id.* The complaint alleged that the defendant manufacturer had concealed and misrepresented information about the safety of the drug, but also that the physician was negligent for failing to monitor the patient and warn of the drug's side effects. *See id.* The plaintiffs in *Baisden* repeatedly alleged that the manufacturer concealed and misrepresented facts regarding the drug, and yet also asserted that the doctor knew or should have known the truth in spite of the manufacturer's misrepresentations. *See id.* Observing the contradictory and irreconcilable nature of those positions, the district court ruled that the plaintiff had fraudulently joined the physician and disregarded the physician's local citizenship. *See id.*

Numerous other courts have reached the same conclusion as the court in *Baisden* – that plaintiffs should not be able to defeat diversity jurisdiction when it is clear that their claims against the in-state defendant are wholly inconsistent with the substance of their lawsuit.[3]

For this reason too, McKesson is fraudulently joined.

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[3] *See In re PPA* , slip op. at 6-7 (pharmacy defendant fraudulently joined where the allegations that "manufacturer defendants concealed material facts regarding PPA through product packaging, labeling, advertising, promotional campaigns and materials, and other methods . . . directly undermines and contradicts the idea that [the resident retail defendant] had knowledge or reason to know of alleged defects"); *In re Rezulin Prod. Liab, Litig.*, 133 F. Supp. 2d 272, 290 (S.D.N.Y. 2001) (resident retail pharmacies facing failure to warn claims fraudulently joined where "the theory underlying the complaint [was] that the manufacturer defendants hid the dangers of Rezulin from plaintiffs, the public, physicians, distributors and pharmacists – indeed, from everyone"); *Wiggins v. Am. Home Prods. Corp.*, No. CV-01-J-2303-NW, 2001 WL 34013629 (N.D. Ala. Oct 2, 2001) (in-state pharmacy was fraudulently joined where plaintiffs made no reasonable allegation against the pharmacy); *In re Rezulin Prods. Liab. Litig.*, 2003 U.S. Dist. LEXIS 28, MDL No. 1348, Case No. 02-Civ. 3583 (S.D.N.Y. Jan. 6, 2003) (finding fraudulent joinder where the failure to warn claims against a physician were premised on knowledge allegedly withheld).

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c. Under California Law Plaintiffs Cannot Prove a Cause of Action Against McKesson For Plaintiffs' Alleged Injuries

Finally, even if McKesson had distributed plaintiffs;' Avandia, it would still be fraudulently joined because there would still be no basis for holding McKesson liable under California law.

Under no reasonable view of California law can a wholesale distributor be liable for injuries allegedly caused by defects in a drug it did not make, nor by allegedly inadequate warnings over which it had no control. *See* Yonko Dec. at ¶¶ 6, 7 ("McKesson did not manufacturer, produce, process, test, encapsulate, label, [or] package Avandia®, nor does it make any representations or warranties as to the product's safety or efficacy;" "[McKesson] only delivered the unopened boxes that contained the drug") (Cosner Decl. ISO Removal, Exh. "D"). Arguing that such liability does exist under California law, Plaintiffs rely almost exclusively on a series of Vioxx decisions from a single judge from the Central District of California. *See* Pls'. Br. at p. 6:2-5. Those isolated decisions, however, are not binding on this Court, and as explained below, do not represent correct applications of California law.

California tort law treats prescription drugs differently from other products. For example, California law unequivocally bars strict liability causes of action for design defect in the prescription drug context. *See Brown v. Superior Court*, 44 Cal. 3d 1049, 1061 (1988) ("a drug manufacturer's liability for a defectively designed drug shall not be measured by the standards of strict liability"). In *Brown*, the California Supreme Court held that a manufacturer is not strictly liable or liable for breach of express or implied warranties for injuries caused by a prescription drug "so long as the drug was properly prepared and accompanied by warnings of its dangerous propensities that were either known or reasonably scientifically knowable at the time of distribution." *Id.* at 1069. In California – as in virtually every other state – the duty to warn about a drug's risks runs directly from the manufacturer to the physician (*i.e.* the "learned intermediary"), and then from the physician to the patient. *See Brown*, 44 Cal. 3d at 1061-62, n.9.; *Carlin v.*

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Superior Court, 13 Cal. 4th 1104, 1116 (1996). Accordingly, case law makes clear that, under the "learned intermediary doctrine," distributors such as McKesson owe no duty to individual patients. Because the pharmaceutical company, not the distributor, has a duty to warn physicians of the risks associated with medications and medical devices, courts have repeatedly concluded that distributors are fraudulently joined. *See, e.g., Barlow v. Warner-Lambert Co.*, Case No. CV 03 1647 R (RZx), slip op. at 2 (C.D. Cal. April 28, 2003) ("The Court finds that there is no possibility that plaintiffs could prove a cause of action against McKesson, an entity which distributed this FDA-approved medication [Rezulin] to pharmacists in California;" motion to remand denied); *Skinner v. Warner-Lambert Co.*, Case No. CV 03 1643-R (RZx), 2003 WL 25598915 at *2 (C.D. Cal. April 28, 2003); *Murphy v. E.R. Squibb & Sons, Inc.*, 40 Cal. 3d 672, 680-81 (1985) (under the learned intermediary doctrine, retail pharmacies can have no general duty to warn consumers of effects of prescription drugs); *In re Baycol Prods. Litig.*, MDL No. 1431, Case No. 02-139, slip op. at 3-4 (D. Minn. May 24, 2002) (retail distributor of prescription drugs fraudulently joined); *Schaerrer v. Stewart's Plaza Pharmacy*, 79 P.3d 922, 929 (Utah 2003) (declining to extend duty to warn to retail distributor of prescription diet drug as long as [their] "ability to distribute prescription drugs is limited by the highly restricted FDA-regulated drug distribution system in this country . . ."); *Legg v. Wyeth*, 428 F.3d 1317 (11th Cir. 2005) ("[t]he Multidistrict Litigation Court . . . concluded that this joinder can 'only be characterized as a sham, at the unfair expense not only of [Wyeth] but of many individuals and small enterprises that are being unfairly dragged into court simply to prevent the adjudication of lawsuits against [Wyeth], the real target, in a federal forum.").

Furthermore, pharmaceutical warnings are highly regulated by the Food & Drug Administration ("FDA"), which militates against imposing any separate duty to warn on pharmacies and pharmaceutical distributors. The FDA closely regulates pharmaceutical manufacturing, and it controls the testing of medicines and the methods by which they are marketed, including the contents of warning labels. *Brown*, 44 Cal. 3d at 1059, fn.

12. The federal regulations provide specific requirements for all aspects of the medicine, the standards to be followed in manufacturing (21 C.F.R. §211, *et. seq.*), the standards for wholesale distribution (§203.50), the contents of its labeling, including warnings (§201.57), and permissible representations to be made in advertisements (§202, *et seq.*). The regulations also state that a manufacturer may list only known risks and not theoretical possibilities, and that no prescription medicine may go to a distributor like McKesson unless the labeling complies with federal regulations and is approved by the FDA. *See* 21 C.F.R. §201.57(d); 21 C.F.R. §201.59.

Once the labeling is approved, the information found therein cannot be altered without FDA approval. *See* 21 U.S.C. § 331(k); *Brown v. Superior Court*, 44 Cal. 3d at 1069 n. 12 (noting that the FDA regulates the testing, manufacturing, and marketing of drugs, including the content of their warning labels). Both drug manufacturers and distributors are prohibited from causing the "alteration, mutilation, destruction, obliteration, or removal of the whole or any part of the labeling" of an FDA-approved drug held for sale. 21 U.S.C. §331(k).

As a distributor, McKesson had no duty to warn Plaintiffs, assuming it distributed the Avandia ingested by Plaintiffs in the first place. Nor could McKesson have given additional or different warnings without violating federal law. The FDA approved all Avandia warnings and marketing materials. Had McKesson provided alternative, non-FDA approved warnings, or warnings inconsistent with those approved by the FDA, it would have been in violation of federal law prohibiting false or misleading labeling and the alteration of FDA-approved labeling (21 U.S.C. §§331, subd. (k), (o); 21 U.S.C. §352(a), (f); 21 C.F.R. 201.56, 201.57), and could have resulted in an enforcement action, fines or criminal penalties. 21 U.S.C. §§331, subd. (b), (k), 352, subds. (a), (f), 333, subd. (a). No duty can be found where it requires a party to violate the law to fulfill it.

These authorities lead to two inescapable conclusions that control this motion. First, the distributor McKesson had no duty to warn Plaintiffs of anything and, thus, cannot be held liable to Plaintiffs – even if it did distribute the Avandia that Plaintiffs

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allegedly ingested. Second, not only did McKesson have no duty to Plaintiffs, it could not have given additional warnings even if it wanted to. The FDA approved all Avandia warnings and marketing materials. Had McKesson provided additional, non-FDA approved warnings, or warnings inconsistent with those approved by the FDA, they would have been in violation of federal law prohibiting false or misleading labeling and the alterations of FDA-approved labeling (21 U.S.C. §§ 331, subd. (k), (o); 21 U.S.C. § 352(a), (f); 21 C.F.R. 201.56, 201.57), and could have resulted in an enforcement action, fines or criminal penalties. 21 U.S.C. §§ 331, subd. (b),.(k), 352, subds. (a), (f), 333, subd. (a).

Both the federal regulation of warnings provided with prescription drugs and the common law approach to pharmaceutical product liability claims convey the underlying policy preference that one set of consistent and approved warnings accompany drugs like Avandia. The duty to warn lies with the manufacturer, and any alteration of those warnings by a distributor would violate federal law. As such, Plaintiffs may not proceed against McKesson on a theory of failure to warn.

In short, there is no theory of liability under which Plaintiffs could prevail against McKesson. Accordingly, McKesson's citizenship should be ignored for purposes of the forum defendant rule, and this Court has diversity jurisdiction over this case.

C. This Court Has Federal Question Jurisdiction Based on Plaintiffs' Claims Which Raise Questions Of Federal Law

Since diversity jurisdiction over this matter is clear, GSK need not address in detail the second ground for removal, federal question jurisdiction.

Plaintiffs' complaint contains many assertions that depend on construction and application of federal statutes and regulations, and therefore this Court has federal question jurisdiction over this matter pursuant to 28 U.S.C. § 1331 and the principles set forth in *Grable & Sons Metal Prods., Inc. v. Darue Eng'g & Mfg.*, 545 U.S. 308 (2005).

There are several federal questions in plaintiffs' claims, and it is in the national interest that there be a federal forum for claims that attack the federally-approved

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labeling of a prescription medicine. Count III of the Complaint, for example, explicitly alleges that GSK violated the Food Drug and Cosmetic Act, 21 U.S.C. § 301 et seq., and that GSK illegally promoted an unsafe drug for public use and failed to warn the FDA, doctors and consumers of the risks of Avandia. *See* Pls' Compl. at ¶¶ 26-28, 33, 55 (Cosn. Decl. ISO Removal, Exh. "A").[4]

To the extent this Court seeks further exposition of the presence of federal issues and federal question jurisdiction, GSK requests leave to file an additional brief in which to present its position.

IV. CONCLUSION

This Court has both diversity jurisdiction and federal question jurisdiction over Plaintiffs' Complaint. Accordingly, Plaintiffs' Motion to Remand should be denied.

Dated: December 26, 2007

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/S/
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[4] GSK notes that plaintiffs have made several unsupportable arguments in addressing the federal aspects of this case. For example, plaintiffs state that the burden of updating the label rests squarely with the defendant and argues that the preemption defense was "abolished," when, "[o]n September 27, 2007, the Prescription Drug User Free [sic] Authorization Act (PDUFA), H.R. 3580, was signed into law [and], for the first time, placed the burden of updating the warning label of a prescription drug squarely on the drug company." Pl.'s Br. at 11-12. The Act that was signed by President Bush on September 27, 2007 is entitled the Food and Drug Administration Amendments Act of 2007, 110 P.L. 85; 121 Stat. 823 (FDAAA), codified at 21 U.S.C. §355. It is evident from the plain language of the provision in question that the FDAAA does not alter the responsibility of the drug manufacturer with respect to labeling, and it has absolutely no effect on any preemption defense. *See* 21 U.S.C. § 355(o)(4)(I).

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